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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,812	02/04/2002	Richard J. Greff	29985/05-117A	8436

57726 7590 03/07/2008

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
03/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/068,812	GREFF, RICHARD J.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2007* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-38 and 42* is/are pending in the application.

4a) Of the above claim(s) *34-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-33 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 09/28/2007.

Claims 22-38, and 42 are pending.

The following restriction requirement is necessitated by applicants' amendment:

Election/Restrictions

1. The amended claim 34-38 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the amended claims 34-38 are directed to method of hydration the gelatin composition, and from specification such a method is for assessment of aqueous fluid uptake of the gelatin for comparison purposes. Claims 34-38 as currently amended are not directed to method of use the composition for claim 22, in contrast, claims 34-48 are directed to hydration method of the composition. The product claims 22-33, and 42 and the method claims 34-38 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different function and different mode of operation because the product of claim 22

is used as wound dressing in vivo, while the method of claim 34 is assessment method of hydration of a composition in aqueous solution in vitro.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 34-38 area withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 22-33, and 42 are included in the prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 22-29, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 02-182259 (259).

JP '259 teaches composition comprising cross linked gelatin, and solution comprising surfactant impregnated into the cross linked gelatin (see the provided abstract). The composition comprises 1-50 % of gelatin in aqueous solution and from 0.1 % to 30 % of the aqueous solution is the surfactant (page 5, last paragraph; page 6, first full paragraph). The reference disclosed in the process of making the composition, the gelatin solution is prepared, then, the surfactant is added followed by foaming and drying, i.e. evaporation of the solvent (page 6, second full paragraph; page 10, operational example 1). The composition easily dissolves in blood or body fluids, i.e. bioabsorbable (page 7, third line). The surfactants disclosed by the reference include sodium lauric sulfuric acid, polyethylene glycol alkyl ether and sorbitan fatty acid ester (page 7, second full paragraph). The material disclosed by the reference that comprises cross-linked gelatin and the same wetting agent, is expected to decrease the hydration time of the cross-linked gelatin that claimed in claims 22 and 34. Furthermore, on page 5, lines 25-27 of the present disclosure, applicants disclosed that the hydration time is the time needed to prepare the gelatin for use, and the reference disclosed on page 11, third full paragraph that hemostatic composition showed slight swelling and arrested bleeding in 60 seconds, i.e. the composition was ready for use.

The difference between JP '259 and the present invention is that JP '259 does not explicitly teach coating of the wetting agent on the surface of the cross-linked gelatin. However, the reference disclosed soaking of gelatin sponge in solution wherein surfactant is added to this solution, page 6, lines 8-12). After drying the mixture of gelatin and the surfactant of the reference, it is expected to have some wetting agents on the surface of the product, which reads on partially coating. In any event, the presence of the wetting agent as a coating on the surface does not impart patentability of the claims, absent evidence to the contrary. No superior and unexpected results of record obtained by coating the wetting agent on the surface of the gelatin versus incorporating the wetting agent into the gelatin.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cross-linked gelatin sponge soaked in wetting agent as disclosed by JP '259, and it is expected to have the wetting agent on the surface of the product after drying as a partial coating.

Response to Arguments

5. Applicant's arguments filed 09/28/2007 have been fully considered but they are not persuasive. Applicants argue that Yasushi teaches the hemostatic plaster is formed by: (1) forming an aqueous gelatin solution; (2) adding a surfactant to the gelatin solution; (3) stirring the solution to form foam and freeze-drying the foam to obtain a gelatin sponge; and (4) soaking the sponge in an organic solvent solution containing a cross- linking agent. Applicant argue that Yasushi does not teach or suggest the

soaking of a gelatin sponge in a surfactant solution and therefore does not teach the coating of a surfactant or wetting agent on the gelatin sponge. Further applicants argue that Yasushi's surfactant is not coated on the surface of the gelatin sponge because the surfactant does not form a continuous layer over the gelatin sponge. Yasushi's surfactant is evenly impregnated throughout the gelatin sponge. Although a small portion of Yasushi's surfactant may be present on the surface of the gelatin sponge, it still cannot form a continuous layer thereon as required by the definition of "coating". As a result, one of ordinary skill in the art would not consider Yasushi's surfactant as a "coating" or "'partial coating". Yasushi fails to disclose each element of the claims.

In response to this argument, applicants' attention is directed to the scope of claims 22-29 and 42 that is directed to composition comprising crosslinked gelatin sponge and wetting agent coating substantial portion of the gelatin sponge, and Yasushi teaches crosslinked gelatin foam impregnated with the wetting agent, and applicants themselves admit that a small portion of Yasushi's surfactant may be present on the surface of the gelatin sponge, and this reads on "substantial portion of the surface is coated with wetting agent". In absence of definition of "substantial portion is coated" the disclosure of the reference reads on the claims. However, applicants still argue that smell portion of the wetting agent on the surface cannot form a continuous layer thereon as required by the definition of "coating". In response to this argument that the reference fails to show "continuous coating", such limitation is not recited in the rejected claims, the claims recite "substantial portion is coated". Although the claims are interpreted in

light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Regarding method of making disclosed by the reference, the present claims are directed to product, and the elements of the product as disclosed by the reference, and the method of the reference does not impart patentability to the product claims and patentability is determined by the product itself. The reference method provides crosslinked gelatin foam impregnated with wetting agent, therefore, having some wetting agent on the surface of the gelatin foam, as applicants admit.

6. Claims 30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '259 in view of US 6,603,061 ('061).

The teachings of JP '259 are discussed above. However, JP '259 does not teach that the composition is sterilized and packaged as claimed by claim 30, or the composition comprising thrombus enhancing agent as claimed in claim 32, or antimicrobial agent as claimed in claim 33.

US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin, plasticizer and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition further comprises active agent such as antibiotics and hemostatic agents including thrombin and clotting factors (col.11, lines 16-35). The composition can be in the form of sterile package (col.3, lines 33-34; col.5, lines 6-10, 25-35; col.8, lines 32-36).

Therefore, it would have been obvious to one having ordinary skill in the art at he time of the invention to provide the hemostatic composition disclosed by JP '259 and add antimicrobial and/or clotting factors as disclosed by US '061, motivated by the teaching of US '061 that such agents are beneficial for hemostasis, with reasonable expectation of having hemostatic composition comprises cross-linked gelatin and wetting agent and further comprises antimicrobial and/or clotting factors that are beneficial for hemostasis. Additionally, one having ordinary skill in the art would have been motivated to sterilize and package the gelatin sponge produced by JP '259 as disclosed by US '061, motivated by the logic of the wound dressing art that sterilization and package of gelatin material will be safer to use on the wound or bleeding site, with reasonable expectation of having sterile packaged gelatin sponge incorporating wetting agent that is safe to apply to bleeding site or wound.

7. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP '259 in view of EP 5568 334 ('334).

The teachings of JP '259 are discussed above. However, JP '259 does not teach that the composition comprising growth factor as instantly claimed claim 31.

EP '334 teaches collagen containing sponge comprising cross linked gelatin and active agent, preferably growth factors which enhanced wound healing and nerve regeneration (abstract; col.5, lines 22-30).

Therefore, it would have been obvious to one having ordinary skill in the art at he time of the invention to provide hemostatic composition comprising cross linked gelatin

and wetting agent as disclosed by JP '259, and add growth factors to the composition as disclosed by EP '334, motivated by the teaching of US '334 that growth factors are preferred active ingredient to be added to hemostatic gelatin wound treating composition because growth factors enhance wound healing and nerve regeneration, with reasonable expectation of having composition comprising cross linked gelatin, wetting agent and growth factors wherein the composition enhances wound healing and nerve regeneration successfully.

Response to Arguments

8. Applicant's arguments filed 09/28/2007 have been fully considered but they are not persuasive. Applicants traverse the rejection of claims 30 and 32-33 over Yasushi in view of Wallace (US '061); and the rejection of claim 31 over Yasushi in view of Song (EP '334) by arguing that the deficiencies of Yasushi are not addressed by Wallace nor Song and they do not teaches or suggests a surfactant or wetting agent coated on the surface of a gelatin sponge.

In response to theses argument, applicants' attention is directed to the scope of the present claims that are directed to product and the elements of the product are disclosed by Yasushi in absence of definition of "substantial portion is coated", as set forth in section 5 of this office action. Wallace is relied upon for the solely teaching that active hemostatic agents can be incorporated into wound dressing, and for teaching the packaging. Song is relied upon for the solely teaching of benefit of growth factor to the

wound. It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.,* 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions."

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611